Merus Provides Clinical Updates for MCLA-117 and MCLA-158 Programs

January 4, 2018

- IND submitted to U.S. FDA for MCLA-117 in AML -

- First CTA approval for MCLA-158 received in European country -

UTRECHT, The Netherlands, Jan. 04, 2018 (GLOBE NEWSWIRE) -- Merus N.V. (Nasdaq:MRUS), a clinical-stage immuno-oncology company developing innovative bispecific antibody therapeutics (Biclonics®), today announced the submission of an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) for MCLA-117 for the potential treatment of acute myeloid leukemia (AML) and the approval of a Clinical Trial Application (CTA) in Belgium for MCLA-158 for the potential treatment of metastatic colorectal cancer.

"The filing of an IND for MCLA-117 and the first CTA approval for MCLA-158 represent key steps forward for both programs as we continue to progress our robust pipeline of proprietary bispecific antibodies in the clinic with the goal of addressing significant unmet medical needs," said Ton Logtenberg, Ph.D., Chief Executive Officer of Merus. "We look forward to the advancement of both Biclonics® in 2018, including the initiation a Phase 1 first-in-human trial of MCLA-158 in Belgium planned for this quarter."

Merus today announced that it has submitted an IND application to the U.S. FDA for MCLA-117, the Company's T-Cell Engager Biclonics ®, designed to specifically bind to CD3, a cell-surface molecule present on T cells, and CLEC12A, a cell-surface molecule present on AML cells and stem cells. MCLA-117 is currently being studied in an ongoing Phase 1, first-in-human, dose escalation clinical trial in Europe in AML patients with relapse or refractory disease. Upon acceptance of the IND by the U.S. FDA, Merus plans to open sites for this trial in the United States.

The Company also announced approval of a CTA in Belgium, one of the several European countries where Merus has filed a CTA and where it plans to first initiate a Phase 1, first-in-human clinical trial of MCLA-158. MCLA-158 is an ADCC-enhanced Biclonics® designed to bind to cancer stem cells expressing leucine-rich repeat-containing G protein-coupled receptor 5 (Lgr5) and epidermal growth factor receptors (EGFR). The trial, which will focus initially in patients with metastatic colorectal cancer, is anticipated to start during the first quarter of 2018. Merus plans to file an IND for MCLA-158 with the U.S. FDA in the first quarter of 2018.

About Merus N.V.

Merus is a clinical-stage immuno-oncology company developing innovative full-length human bispecific antibody therapeutics, referred to as Biclonics®. Biclonics®, which are based on the full-length IgG format, are manufactured using industry standard processes and have been observed in preclinical studies to have similar features as conventional monoclonal antibodies, such as long half-life and low immunogenicity. Merus' most advanced bispecific antibody candidate, MCLA-128, is expected to soon be evaluated in a Phase 2 combination trial in two metastatic breast cancer populations. MCLA-128 is also being evaluated in a Phase 1/2 clinical trial in Europe in gastric, ovarian, endometrial and non-small cell lung cancers. Merus' second most advanced bispecific antibody candidate, MCLA-117, is being developed in a Phase 1 clinical trial in patients with acute myeloid leukemia. The Company also has a pipeline of proprietary bispecific antibody candidates in preclinical development, including MCLA-158, which is designed to bind to cancer stem cells and is being developed as a potential treatment for colorectal cancer and other solid tumors, as well as MCLA-145, which is designed to bind to PD-L1 and a non-disclosed second immunomodulatory target and is being developed in collaboration with Incyte Corporation. For additional information, please visit Merus' website, www.merus.nl.

Forward Looking Statement

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including without limitation statements regarding the progress of Merus' robust pipeline of proprietary bispecific antibodies in the clinic with the goal of addressing significant unmet medical needs, the advancement of MCLA-117 and MCLA-158 through 2018, including the timing of initiating clinical trials, plans to open sites in the U.S. for the ongoing Phase 1 clinical trial of MCLA-117, the initial focus on metastatic colorectal cancer for the Phase 1 clinical trial for MCLA-158 and filing an IND in the U.S. for MCLA-158 in the first quarter of 2018, the timing of the Phase 2 combination trial of MCLA-128 in metastatic breast cancer and the potential of MCLA-158 to treat colorectal cancer and other solid tumors.

These forward-looking statements are based on management's current expectations. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, the following: our need for additional funding, which may not be available and which may require us to restrict our operations or require us to relinquish rights to our technologies or Biclonics® and bispecific antibody candidates; potential delays in regulatory approval, which would impact our ability to commercialize our product candidates and affect our ability to generate revenue; the lengthy and expensive process of clinical drug development, which has an uncertain outcome; the unpredictable nature of our early stage development efforts for marketable drugs; potential delays in enrollment of patients, which could affect the receipt of necessary regulatory approvals; our reliance on third parties to conduct our clinical trials and the potential for those third parties to not perform satisfactorily; we may not identify suitable Biclonics® or bispecific antibody candidates under our collaboration with Incyte or Incyte may fail to perform adequately under our collaboration; our reliance on third parties to manufacture our product candidates, which may delay, prevent or impair our development and commercialization efforts; protection of our proprietary technology; our patents may be found invalid, unenforceable, circumvented by competitors and our patent applications may be found not to comply with the rules and regulations of patentability; we may fail to prevail in existing and potential lawsuits for infringement of third-party intellectual property; and our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks.

These and other important factors discussed under the caption "Risk Factors" in our Annual Report on Form 20-F filed with the Securities and Exchange Commission, or SEC, on April 28, 2017, and our other reports filed with the SEC, could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any such forward-looking statements represent management's estimates as of the date of this press release. While we may elect to update such forward-looking statements at some point in the future, we disclaim any obligation to do so, even if subsequent events cause our views to change, except as required under applicable law. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this press release.

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